

Substitute for Form 1449/A/PTO

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

## Complete if Known

Application Number	09/825,012
Filing Date	April 3, 2001
First Named Inventor	Robert YOUNG
Group Art Unit	1642
Examiner Name	Canella, K.
Attorney Docket Number	43191/256808 (16210)

Sheet 1 of 4

## U.S. PATENT DOCUMENTS

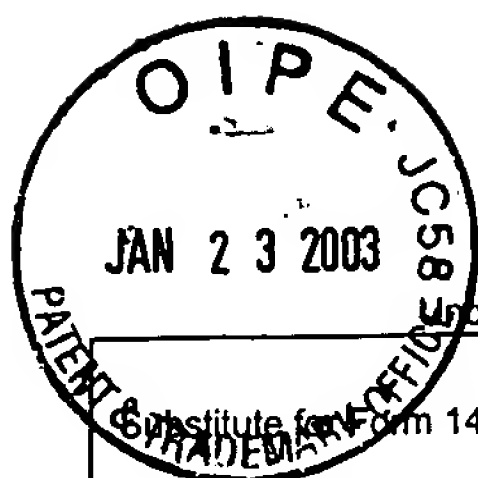
Examiner Initials	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
KAC	1	5,955,073		Rybak et al.	09-21-1999	

## FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
KAC	2	EP	0 239 400 A					
	3	EP	0 302 473 A					
	4	EP	0 369 816 A					
	5	EP	0 781 845 A					
	6	WO	88/05054					
	7	WO	88/07378					
	8	WO	88/09344					
	9	WO	89/07268					
	10	WO	90/05142					
	11	WO	90/12319					
	12	WO	91/07500					
	13	WO	91/11201					
	14	WO	91/16069					
	15	WO	92/04380					
	16	WO	94/11508					
	17	WO	94/15644					
	18	UK	2,289,679 A					

Examiner Signature	<i>Karen Q. Canella</i>	Date Considered	10/17/03
-----------------------	-------------------------	--------------------	----------

<sup>1</sup>Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent document, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language translation is attached.

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

**Complete if Known**

Application Number	09/825,012
Filing Date	April 3, 2001
First Named Inventor	Robert YOUNG
Group Art Unit	1642
Examiner Name	Canella, K.
Attorney Docket Number	43191/256808 (16210)

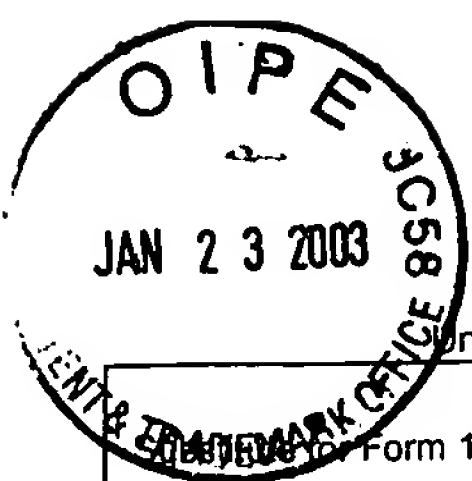
Sheet 2 of 4

**OTHER INFORMATION - NON PATENT LITERATURE DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
KAL	19	J. ARKLIE et al., "Differentiation Antigens Expressed by Epithelial Cells in the Lactating Breast are Also Detectable in Breast Cancer", Int. J. Cancer, 28, 23-29 (1981).	
	20	K. D. BAGSHAW, "Antibody Directed Enzymes Revive Anti-Cancer Prodrugs Concept", Br. J. Cancer, 56, 531-532 (1987).	
	21	K.D. BAGSHAW et al., "A Cytotoxic Agent can be Generated Selectively at Cancer Sites", Br. J. Cancer, 58, 700-703 (1988).	
	22	Marc BETTER et al., "Escherichia coli Secretion of an Active Chimeric Antibody Fragment", Science 240, 1041 (May 20 1988).	
	23	Robert E. BIRD et al., "Single-Chain Antigen-Binding Proteins", Science 242, 423 (October 21 1988).	
	24	Mark I. COCKETT et al., "The Use of Engineered E1A Genes to Transactivate the hCMV-MIE Promoter in Permanent CHO Cell Lines", Nucleic Acids Research, Vol. 19, No. 2, 319-325 (1990).	
	25	Sandra GENDLER et al., "A Highly Immunogenic Region of a Human Polymorphic Epithelial Mucin Expressed by Carcinomas is Made up of Tandem Repeats", J. Biol. Chem, 236, 12820-12823 (1988).	
	26	Sandra J. GENDLER et al., "Molecular Cloning and Expression of Human Tumor-Associated Polymorphic Epithelial Mucin", J. Biol. Chem., 265, 15286-93 (1990).	
	27	D. J. HNATOWICH et al., "Patient Biodistribution of Intraperitoneally Administered Yttrium-90-Labeled Antibody", J. Nucl. Med., 29, 1428-1434 (1988).	
	28	Richard C. HUBBARD, M.D. et al., "A Preliminary Study of Aerosolized Recombinant Human Deoxyribonuclease I in the Treatment of Cystic Fibrosis", New Eng. J. Med., 326, 812-815 (1992).	
	29	James S. HUSTON et al., "Protein Engineering of Antibody Binding Sites: Recovery of Specific Activity in an Anti-Digoxin Single-Chain Fv Analogue Produced in Escherichia coli", Proc. Natl. Acad. Sci. USA, 85, 5879 (1988).	
	30	Peter T. JONES et al., "Replacing the Complementarity-Determining Regions in a Human Antibody with Those from a Mouse", Nature, 321, 522-525 (1986).	
	31	H. P. KALOFONOS et al., "Imaging of Tumor in Patients with Indium-111-Labeled Biotin and Streptavidin-Conjugated Antibodies: Preliminary Communication, J. Nucl. Med., 31, 1791-1796 (1990).	

Examiner Signature	Karen A. Canella	Date Considered	10/17/03
--------------------	------------------	-----------------	----------

<sup>1</sup>Unique citation designation number. <sup>2</sup>Applicant is to place a check mark here if English language translation is attached.

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

**Complete if Known**

Application Number	09/825,012
Filing Date	April 3, 2001
First Named Inventor	Robert YOUNG
Group Art Unit	1642
Examiner Name	Canella, K.
Attorney Docket Number	43191/256808 (16210)

Sheet 3 of 4

**OTHER INFORMATION - NON PATENT LITERATURE DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
KAL	32	H. LINARDOU et al., "Deoxyribonuclease I (Dnase I) - A Novel Approach for Targeted Cancer Therapy", Cell Biophysics, 24/25, 243-248 (1994).	
	33	Sherie L. MORRISON et al., "Chimeric Human Antibody Molecules: Mouse Antigen-Binding Domains with Human Constant Region Domains", Proc. Natl. Acad. Sci. USA, 81, 6851-6855 (1984).	
	34	Sherie L. MORRISON, "New Approaches to the Production of Monoclonal Antibodies", Science, 239, G28, 48, 112-113 (1988).	
	35	M. S. NEUBERGER et al. "Antibody Engineering", 8 <sup>th</sup> International Biotechnology Symposium Part 2, 792-799 (1988).	
	36	Michael J. O'SULLIVAN et al., "Comparison of Two Methods of Preparing Enzyme-Antibody Conjugates: Application of These Conjugates for Enzyme Immunoassay", Anal. Biochem., 100, 100-108 (1979).	
	37	G. PAGANELLI et al., "Intraperitoneal Radio-Localization of Tumors Pre-Targeted by Biotinylated Monoclonal Antibodies", Int. J. Cancer, 45, 1184-1189 (1990).	
	38	Lutz RIECHMANN et al., "Reshaping Human Antibodies for Therapy", Nature, 332, 323-327 (1988).	
	39	Susanna M. RYBAK et al., "Cytotoxic Potential of Ribonuclease and Ribonuclease Hybrid Proteins", J. Biol. Chem., 266, 21202 (1991).	
	40	Peter D. SENTER et al., "Anti-Tumor Effects of Antibody-Alkaline Phosphatase Conjugates in Combination with Etoposide Phosphate", Proc. Natl. Acad. Sci. USA, 85, 4842 (1988).	
	41	Steven SHAK et al., "Recombinant Human Dnase I Reduces the Viscosity of Cystic Fibrosis Sputum", Proc. Natl., Acad. Sci. USA, 87, 9188-9192 (1990).	
	42	Dominick SINICROPI et al., "Colorimetric Determination of Dnase I Activity with a DNA-Methyl Green Substrate", Analyt. Biochem., 222, 351-358 (1994).	
✓	43	Arne SKERRA et al., "Assembly of a Functional Immunoglobulin F <sub>v</sub> Fragment in <i>Escherichia coli</i> ", Science, 240, 1038 (1988).	

Examiner  
SignatureDate  
Considered

10/17/03

<sup>1</sup>Unique citation designation number. <sup>2</sup>Applicant is to place a check mark here if English language translation is attached.



<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (use as many sheets as necessary)		<b>Complete if Known</b>	
		Application Number	09/825,012
		Filing Date	April 3, 2001
		First Named Inventor	Robert YOUNG
		Group Art Unit	1642
		Examiner Name	Canella, K.
Sheet 4	of 4	Attorney Docket Number	43191/256808 (16210)

**OTHER INFORMATION - NON PATENT LITERATURE DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
KAL	44	Joyce TAYLOR-PAPADIMITRIOU et al., "Monoclonal Antibodies to Epithelium-Specific Components of the Human Milk Fat Globule Membrane: Production and Reaction with Cells in Culture", Int. J. Cancer, 28, 17-21 (1981).	
	45	Martine VERHOEYEN et al., "Reshaping Human Antibodies: Grafting an Antilysozyme Activity", Science, 239, 1534-1536 (1988).	
	46	M.E. VERHOEYEN et al., "Reshaping Human Monoclonal Antibodies for Imaging and Therapy", Disease Markers, 9, 197-203 (1991).	
	47	E. Sally WARD et al., "Binding Activities of a Repertoire of Single Immunoglobulin Variable Domains Secreted From <i>Escherichia coli</i> ", Nature, 341, 544 (1989).	
	48	Greg WINTER et al., "Man-Made Antibodies", Nature, 349, 293-299 (1991).	
	49	Andrew F. WORRALL et al., "The Chemical Synthesis of a Gene Coding for Bovine Pancreatic Dnase I and Its Cloning and Expression in <i>Escherichia coli</i> ", J. Biol. Chem., 265, 21889-21895 (1990).	
	50	N. Martin YOUNG et al., "Thermal Stabilization of a Single-Chain Fv Antibody Fragment by Introduction of a Disulphide Bond", FEBS Lett., 377, 135-139 (1995).	
↓	51	Robert J. YOUNG et al., "A Dnase I Based Immunotoxin for Tumor Therapy", Proc. Of the American Assoc. for Cancer Research Annual., 41, 289 (2000).	
KAL	52	Raymond J. OWENS et al., "The Genetic Engineering of Monoclonal Antibodies", J. Immunol. Meth., 168, 149-165 (1994).	

Examiner Signature	<i>Karen A. Canella</i>	Date Considered	10/17/03
--------------------	-------------------------	-----------------	----------

<sup>1</sup>Unique citation designation number. <sup>2</sup>Applicant is to place a check mark here if English language translation is attached.